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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,565	12/21/2001	Oscar M. Bassinson	6739	9996

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EXAMINER

JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/027,565	Applicant(s) BASSINSON, OSCAR M.	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26,29-32,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 27,28,33 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26,29-32,34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' Request for Continued Examination filed on March 16, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims recite that the card-like base must be inedible. The Examiner fails to see where in the Specification the requirement for the card base to be inedible is described. The word inedible does not appear in the Specification and the invention is not described in such a way that would exclude the use of edible substrates for the invention. Therefore, it is the position of the Examiner that the term "inedible" constitutes new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 9, 10, 12, 13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Moir et al. (US 4751934). Moir teaches a card-like base wherein a powder of a pharmaceutical is printed onto the card base and covered with a removable layer (Col. 1, lines 31-38; Col. 2, lines 39-66). The powder formulation is wetted with a solvent and printed onto the card base (Col. 3, lines 11-22). An adhesive is printed onto the perimeter of the base and a top protective layer is laminated to the card base (Col. 3, lines 23-38). Therefore, the Moir reference anticipated instant claims 1, 4, 5, 9, 10, 12, 13 and 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-26,29-32,34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellstrom alone or in combination with BE 637363A. Hellstrom teaches an individualized pharmaceutical package comprising a relatively rigid backing

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member with a depression therein and an item for dispensing positioned with a central depressed area of said backing member and a membrane stretched over the item and joined at the periphery of the backing member (Col. 5, lines 46-60; Col. 6, lines 9-18; Col. 14, Claims 1 & 2). The reference teaches that the item included in the package can be a tablet, capsule, pill, liquid, semiliquid or powder (Col. 5, lines 46-60; Col. 8, lines 51-75). The liquids, semiliquids and powder are contained in a cup attached to the backing member (Col. 8, lines 51-75). Hellstrom does not limit the active agents that can be administered with such a package system.

Hellstrom does not expressly teach that the powder formulation is absorbed or adhered onto the backing member with the use of a binding agent. Hellstrom further does not expressly teach the exact active agents recited in the instant claims to be administered from the package. Hellstrom further does not teach that the backing member is in the size and shape of a credit card.

It is the position of the Examiner that the particular active agent to be dispensed with said package system is not critical. In addition, the size and shape of the backing member also does not appear to be critical. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispense various active agent from a package system such as described by Hellstrom wherein the size and shape of the backing member is varied. One would be motivated to vary the drug to be dispensed to prepare different individualized packages for the various drugs or actives that one would need to carry with them. In addition, one would vary the size and shape of backing member for aesthetic reasons as well as for convenience, depending

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upon the form of the active agent. It is the position of the Examiner that these are limitations that would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

Further, it is the position of the Examiner that the attaching of the powder directly to the card with a binding agent is also not critical. The prior art teaches various forms of the package system that include tablets, or capsule or powders. The Examiner sees no criticality in binding the drug directly to backing member. The prior art appears to teach the same general concept of the package system – a backing member, an active formulation and a film covering the active formulation. The prior art provides a package that is easily transported and provides easy administration of the formulation contained within the package.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to vary the form of the active composition that is contained within the package of the Hellstrom. One of ordinary skill would be motivated to do so to most effectively deliver the desired active agent to the host.

Therefore, the instant claims are rendered obvious over the prior art absent a clear showing of unusual or unexpected results. The results must be those that accrue from the specific limitations.

In addition, Hellstrom can be combined with BE 637363 A (hereinafter '363) reference. The teachings of Hellstrom are discussed above. Hellstrom does not

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expressly teach that the active agent is attached to the backing member with a binding agent.

'363 teaches a medicament composition in which an active agent is absorbed or attached to inert fiber of paper with a water-soluble binding agent (See abstract). The paper product can be provided in the form of a stamp or in other convenient forms so that any dose may be conveniently administered.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach an active agent with a binding agent to a backing member made from paper to administer a desired drug.

One would have been motivated to do so to reduce research time and research costs in developing a tablet or capsule formulation.

Again, it is the position of the Examiner that the particular active agent to be dispensed with said package system is not critical. In addition, the size and shape of the backing member also does not appear to be critical. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispense various active agent from a package system such as described by Hellstrom wherein the size and shape of the backing member is varied.

One would be motivated to vary the drug to be dispensed to prepare different individualized packages for the various drugs or actives that one would need to carry with them. In addition, one would vary the size and shape of backing member for aesthetic reasons as well as for convenience, depending upon the form of the active agent. It is the position of the Examiner that these are limitations that would be routinely

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determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

Therefore, the instant claims are rendered obvious over Hellstrom in combination with '363.

Response to Arguments

Applicant's arguments filed March 16, 2004 have been fully considered but they are not persuasive. Applicants argue that the prior art fails to teach or suggest a medication card on which a medication is adhered or coated directly on to a surface of a base, applied directly to a surface of a base or otherwise retained by the backing member alone. Still further, applicants argue that the prior art teaches a different method of using the card to dispense the medication contained therein.

In response, the Examiner would first like to state that the claims are given the broadest possible interpretation when examined. The broadest independent claims recite a card-like base form, a surface upon which the card is in contact with the medication composition and a cover that is defined as removable.

The Examiner fails to see the unusual or unexpected result of adhering the composition onto the card-like base as opposed to also having a recess that contains a powder composition that is administered to the mouth of the user. The cards of the prior art and the instant claims are used in the same manner and for the same purpose – to administer a powder formulation of the mouth of the user of the composition. The cards themselves are similar size to be carried easily for convenient administration

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when needed. Applicants have not shown any unusual or unexpected result from adhere the composition on the card.

As for the method of delivering a medication, the prior art teaches that the card is formed with purpose of dispensing the medication contained therein to the patient. At column 3, lines 12-16, the reference states that the composition to be dispensed can be dispensed directly into the patient's mouth. When this teaching is taken in consideration with the above comments, the Examiner fails to see the difference in the method of delivering the medication. As stated above, the prior art teaches or suggests the limitations of the broadest interpretation of the instant claims and teaches that the device can be used to dispense the medication directly into the patient's mouth.

The addition of the limitation that the card must be inedible has been deemed new matter. Therefore, any arguments regarding such limitation is unpersuasive.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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